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SEP 2 9 2003

K030003

SUMMARY OF 510(K) SAFETY AND EFFECTIVENESS INFORMATION

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The ATAC Direct Bilirubin Reagent Kit is intended for the quantitative determination of conjugated bilirubin in serum and plasma. Conjugated bilirubin results are used for the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block. The ATAC Direct Bilirubin Reagent determines conjugated bilirubin through its reaction with diazotized sulfanilic acid to form a red-purple complex. The resulting increase in absorbance at 546 nm is proportional to the direct bilirubin concentration in the sample.

The ATAC Direct Bilirubin Reagent Kit, which contains both reagent and calibrator, is substantially equivalent to the Trace Direct Bilirubin Reagent, product UG38 (Trace Scientific, Ltd. of Melbourne, Australia) calibrated with the Sigma Bilirubin Calibrator, Total and Direct, product no. B8652 (Sigma Diagnostics, Inc. St. Louis, MO). The effectiveness of ATAC Direct Bilirubin Reagent Kit on the ATAC 8000 Random Access Chemistry System is shown in the following studies.

The recovery of conjugated bilirubin using the ATAC Direct Bilirubin Reagent is linear from 0.1 to 20 mg/dL, as shown by the recovery of linearity standards that span the usable range. Regression statistics compare standard recoveries to standard values. These statistics are shown below.

(ATAC Recoveries) = 0.11 mg/dL + 6.66 x (Standard Factor), $r = 0.999$, $s_{y.x} = 0.29$ mg/dL, $n = 18$

Precision is demonstrated by the replicate assay of commercially available control serum. Precision statistics, calculated analogous to the method described in NCCLS Guideline EP3-T, are shown below.

Precision of Conjugated Bilirubin Recoveries in mg/dL

			Within Run		Total	
Sample	n	mean	1SD	%CV	1SD	%CV
Serum 1	60	0.9	0.10	10.3%	0.09	9.2%
Serum 2	60	3.8	0.11	3.0%	0.13	3.4%
Serum 3	60	6.7	0.12	1.9%	0.18	2.7%

Mixed serum and plasma specimens, collected from adult patients, were assayed in duplicate for conjugated bilirubin using the ATAC 8000 Random Access Chemistry System and another commercially available method. Each pair of duplicate assays were examined and five specimens were excluded for poor reproducibility. The first assay values for the remaining duplicates were compared by Deming regression. Two additional results were excluded because their residuals exceeded 6 standard errors of regression. Regression statistics for the accepted results are shown below.

ATAC 8000 = -0.10 mg/dL + 1.143 x Competitive Reagent
$s_{y.x} = 0.32$ mg/dL $n = 96$ range = 0.0 - 17.5 mg/dL

The detection limit of 0.1 mg/dL is documented through the repetitive assay of a diluted serum pool. The observed total standard deviation of 125 results over 25 runs was 0.09 mg/dL. Consequently, the detection limit is reported as the round-off error of the assay.

The 5 day onboard reagent stability and calibration stability claims are documented through the assay of serum controls over the claimed periods. In all cases, estimates of the total imprecision of conjugated bilirubin recoveries over the test periods are less than 0.15 mg/dL or 3%.

The 14 day reconstituted stability claim is documented through the assay of serum pools and linearity standards. Observed shifts in recoveries over the 14 day period are less than 0.1 mg/dL or 6%.

Wynn Stocking
Manager of Regulatory Affairs
June 30, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 2 9 2003

Mr. Wynn Stocking
Manager, Regulatory Affairs
Elan Diagnostics
1075 W. Lambert Road – Suite D
Brea, CA 92821

Re: k030003
Trade/Device Name: ATAC Direct Bilirubin Reagent and Calibrator
Regulation Number: 21 CFR 862.1110
Regulation Name: Bilirubin (total or direct) test system
Regulatory Class: Class II
Product Code: CIG; JIS
Dated: June 30, 2003
Received: July 1, 2003

Dear Mr. Stocking:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030003

Device Name: ATAC Direct Bilirubin Reagent and Calibrator

Indications for Use:

The ATAC Direct Bilirubin Reagent Kit, which contains both reagent and calibrator, is intended for use with the ATAC 8000 Random Access Chemistry System as a system for the quantitative determination of conjugated bilirubin in serum and plasma. Conjugated bilirubin results are used for the diagnosis and treatment of liver, hemolytic hematological, and metabolic disorders, including hepatitis and gall bladder block.

This reagent is intended to be used by trained personnel in a professional setting and is not intended for home use.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K030003

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)